PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of	Docket No: Q65952
Nobuhiko OGURA	
Appln. No.: 09/944,175	Group Art Unit: 1639
Confirmation No.: 9850	Examiner: Christopher M. GROSS

Filed: September 4, 2001

For: BIOCHEMICAL ANALYZING METHOD, BIOCHEMICAL ANALYSIS APPARATUS, BIOCHEMICAL ANALYSIS UNIT USED THEREFOR AND TARGET DETECTING APPARATUS FOR DETECTING TARGET FROM BIOCHEMICAL ANALYSIS UNIT

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the provisions of 37 C.F.R. § 41.37, Appellant submits the following:

Table of Contents

I. REAL PARTY IN INTEREST 3

II. RELATED APPEALS AND INTERFERENCES 4

III. STATUS OF CLAIMS 5

IV. STATUS OF AMENDMENTS 6

V. SUMMARY OF THE CLAIMED SUBJECT MATTER 7

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL 9

VII. ARGUMENT 11

CLAIMS APPENDIX 17

EVIDENCE APPENDIX: 21

RELATED PROCEEDINGS APPENDIX 22

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is FUJI PHOTO FILM CO., LTD., now FUJIFILM CORPORATION. The assignment to Fuji Photo Film Co., Ltd. was recorded by the Assignment Branch of the U.S. Patent and Trademark Office on September 4, 2001 at Reel 012138, Frame 0576, and the assignment to Fujifilm Corporation was recorded by the Assignment Branch of the U.S. Patent and Trademark Office on February 15, 2007 at Reel 018904, Frame 0001.

II. RELATED APPEALS AND INTERFERENCES

Upon information and belief, there are no other prior or pending appeals, interferences, or judicial proceedings known to Appellant, Appellant's representative or the Assignee that may be related to, directly affect or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 1, 2, 4-8 and 10-22 are pending in the application. Claims 1, 2, 4-8 and 10-22 are rejected (*see* Office Action dated February 13, 2007). **Claims 1, 2, 4-8 and 10-22 are on appeal** (*see* attached Claims Appendix).

IV. STATUS OF AMENDMENTS

Amendments were made to the pending claims after issuance of the Final Office Action dated April 10, 2006, and those amendments were entered based on the filing of the Request for Continued Examination of October 10, 2007. No amendments were made to the pending claims after issuance of the Non-Final Office Action dated February 13, 2007.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The present invention relates to a biochemical analyzing method for reliably separating substances derived from a living organism other than the target while detecting only the target, for accurately performing a quantitative analysis in the case of fixing probes on a substrate, for binding a target which is a substance derived from a living organism with the probes fixed on the substrate utilizing hybridization or antigen-antibody reaction, and for detecting the target and performing quantitative analysis even when substances derived from a living organism other than the target are bound with the probes due to similarity in structure in addition to the target or instead of the target. See e.g., page 2, lines 2-17 in the specification.

Independent claim 1 (the sole pending independent claim) is directed to a biochemical analyzing method comprising the steps of:

fixing probes selected in advance on a substrate;

binding a target with at least one of the probes using a specific binding reaction to capture the target;

fractionating a combined body of the probe, the captured target and a substance derived from a living organism other than the captured target which is bound with the probe due to a similarity in structure;

detecting only a fractionated target; and

quantitatively analyzing the detected target, wherein the probes are spotted on the substrate and fixed thereon, and the combined body of the probe, the captured target and the substance derived from a living organism other than the target is electrophoresed, thereby being fractionated,

wherein during the fractionating, the combined body of the probe and the captured target and the substance derived from a living organism other than the target is separated into a plurality of fractions based on molecular weight. See e.g., page 7, line 28 to page 8, line 12, page 8, lines 15-24, page 9, lines 21-26, page 22, lines 7-11, page 41, line 25 to page 42, line 2, and page 43, lines 9-13, as well as original claims 1, 3 and 9.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 1, 2, 4-8, and 10-22 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to provide enablement commensurate in scope with the claims. The Examiner maintains that the specification does not provide enablement for fixing probes through "covalent attachment," that it only enables fixing probes through "non-covalent attachment," and that it does not provide a specific definition of "fixing probes" on a substrate covalently or non-covalently (see February 13, 2007 Office Action, page 3, paragraph 1).

The Examiner further characterizes the similar previous rejection (see April 10, 2006 Office Action, pages 2-8) as "directed to...*fractionation* of the covalently immobilized combined body of a probe plus the captured target" (emphasis original; see February 13, 2007 Office Action, page 4, paragraph 2).

The Examiner's position is that such covalently immobilized probes cannot be fractionated and that a covalently immobilized probe will not move in concert with its corresponding target. Moreover, the Examiner reiterates that the Specification does not provide any examples of covalently immobilized probes.

2. Claims 1, 2, 5, 11, 13, 15, 19, and 22 stand rejected under 35 U.S.C. § 102(b), as allegedly being anticipated by Ishii et al., *Nucleic Acids Res.*, 1997, 25(17), pp. 3550-3551, ("Ishii"). The Examiner relies on Ishii as disclosing a method for selecting monoclonal antibodies against a DNA-binding protein complex that comprises each and every element presently claimed.

In particular, the Examiner points to i) the immobilization of mAbs from hybridoma culture supernatants (p. 3550; left column, line 20) as teaching the "fixing probes" step of the

present claims, ii) the measurement of DNA binding activity using biotinylated oligo DNA probe (p. 3550; left column, lines 22-24) as teaching the "binding a target" step of the present claims, iii) the electromobility shift assay (p. 3550; right column, line 4) as teaching the "fractionating a combined body" step of the present claims, iv) the supershift band (p. 3551; Figure 2(b)) as teaching the "detecting only a fractionated target" step of the present claims, and v) the competition analysis (p. 3551; Figure 1(b)) and the optical density analysis (p. 3551; Figure 2(a)) as teaching the "quantitatively analyzing the detected target" step of the present claims (see also April 10, 2006 Office Action, page 9, paragraph 1).

VII. ARGUMENT

Rejection of claims 1, 2, 4-8 and 10-22 under 35 U.S.C. 112, first paragraph, is improper.

Covalent Attachment

The Examiner contends that the specification is enabled only for fixing the probes using a "non-covalent attachment" and not enabled for a "covalent attachment." To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without "undue experimentation." *Plant Genetic Systems v Dekalb Genetics Corporation*, 315 F. 3d 1335 (Fed. Cir. 2003), *citing Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997). Further, enablement is determined as of the effective filing date of the patent. *Id. citing In re Hogan*, 559 F.2d 595, 604 (CCPA 1977).

The scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. *Id. citing In re Fischer, 427 F. 2d 833, 839 (CCPA 1970).*

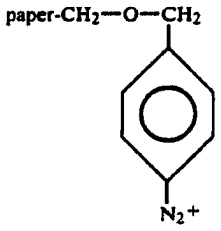
The court in *Plant Genetic Systems*, referring to *In re Hogan*, determined that the claims in *In re Hogan* referred to a seed. The patentee asserted that the claim covers both monocot seeds and dicot seeds. The court determined that at the time of filing of the relevant application, monocots existed and were highly desirable for the claimed purpose. Therefore, they were not unknown at the time of the application.

Like in *In re Hogan*, the techniques for fixing probes on to a substrate were well-known at the time of filing this application, i.e., at least by September 4, 2000, which is the priority date

of the present application. Particularly, the technique of "covalent attachment of a probe onto a substrate" was well known in the art prior to the priority date of the captioned application.

For example, as indicated in the Amendment filed August 10, 2006, U.S. Patent No. 4,512,896 states at col. 2, line 54 to col. 3, line 16:

> "In 1976, it was discovered that single stranded RNA and DNA could be covalently coupled to a cellulose powder substituted by aminobenzyloxymethyl groups which were activated by diazotizing the amine forming diazobenzyloxymethyl (DBM) --cellulose. This filled a gap in hyberdization [sic] technology since RNA does not bind well to nitrocellulose making a Southern Transfer difficult or impossible. In 1977, Alwine, et al. 'Method for Detection of Specific RNAs in Agarose Gels by Transfer to Diazobenzyloxymethyl-Paper and Hybridization with DNA Probes['], Proc. Natl. Acad. Sci. U.S.A., 74: 5350-5354, prepared a cellulosic fibrous sheet (i.e. blotting paper) derivatized with diazobenzyloxymethyl groups, termed DBM-paper, viz.



> which could be used for transfer of a electrophoretically separated pattern of RNA from an agrose gel in a method similar to a Southern Transfer. Aminophenylthioether paper activated to the diazo form (DPT-paper) has also been used. Both papers covalently and irreversibly couple DNA, RNA and proteins."

Therefore, it is clear that the specification reasonably provides enablement for the method of fixing the probe using not only "non-covalent attachment" but also "covalent attachment" of probes selected in advance on a substrate.

Fractionation

Regarding enablement for fractionating a combined body in which the probe is covalently immobilized on a substrate, the Examiner contends that such a covalently immobilized probe cannot be fractionated (See February 13, 2007 Office Action, page 4, paragraph 2). According to the Examiner, a covalently immobilized probe will not move in concert with its corresponding target.

Nowhere does the Applicant impose a limitation on the claimed method that the probe "move in concert with its corresponding target" as the Examiner insists. The Examiner appears to believe that the claimed method requires that the probe, the target, and the other substance must move together as a singular "combined body" in the process of fractionation, as might be the case if the combined body were fractionated from something else.

The Applicant points out, however, that the present method claims "fractionating a combined body"; it is the combined body itself that is fractionated and by definition will not move together as a singular unit.

The Applicant also respectfully submits that fractionation does not require that the probe moves in relation to the substrate on which it is fixed. The claimed method indicates that the combined body is fractionated, thereby separating into various fractions. A covalently immobilized probe need not move in order to be separated, i.e. fractionated, from the other constituents of the combined body such as the target and other substances. A probe can be fractionated from a combined body by remaining stationary while the target and the substance

other than the target move. The separation of these other components of the combined body renders such a combined body "fractionated" even though the fraction containing the probe does not move.

In view of the reasons given above, the Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

Rejection of claims 1, 2, 5, 11, 13, 15, 19 and 22 under 35 U.S.C. 102(b), as being anticipated by Ishii et al. is improper.

The Applicant respectfully submits that Ishii is used for merely selecting monoclonal antibodies against DNZ-binding proteins. MAbs are immobilized onto plates coated with anti-IgG. The DNA binding activity trapped onto the plates are then measured.

However, there is no disclosure for fractionating the target. In other words, Ishii does not disclose or even remotely suggest steps c-e and the wherein clause of claim 1.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP 2131 *citing Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

The Examiner again appears to consider "fractionating" a process that only applies to a singular combined body. For example, the Examiner responded to Applicant's argument with the following reply: "...the claimed method recite [sic] fractionating the combine [sic] bodies of the probe ***and*** target, i.e. the claimed method recite [sic] does not recite fractionating ***only*** the

target. Thus, applicant is arguing limitation [sic] not recited in the claims" (emphasis original; see October 16, 2006 Advisory Action, page 4, paragraph 2).

The Applicant respectfully submits that the plain meaning of "fractionating a combined body" means subjecting a combined body to fractionation. Since fractionation results in various fractions, it is unreasonable for the Examiner to insist that the probe and target must remain in a single fraction.

Ishii teaches precisely that the combined body does not fractionate. According to the method described, "MAbs obtained from this screening would immunoprecipitate the DNA binding complex..." (p. 3550; right column, line 1). This **aggregation** is further reflected in Figure 2(b), which shows a supershifted band that is larger and heavier than the *C. albicans* crude extract in lane 1. Ishii teaches that the combined body moves together in the electromobility shift assay. This unfractionated "fractionation" appears to be how the Examiner construes the present claims.

In any case, Ishii does not teach the steps of "fractionating a combined body," "detecting only a fractionated target," "quantitatively analyzing the detected target," or the wherein clause of claim 1. Claims 2, 5, 11, 13, 15, 19 and 22 are dependent on claim 1, and therefore, are allowable at least for the same reasons.

In view of the reasons given above, the Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. § 102(b).

Unless a check is submitted herewith for the fee required under 37 C.F.R. §41.37(a) and 1.17(c), please charge said fee to Deposit Account No. 19-4880.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

Chid S. Iyer / Bruce R. Crane Reg. No. 33,725

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Chid S. Iyer
Registration No. 43,355

Date: November 12, 2007

CLAIMS APPENDIX

CLAIMS 1, 2, 4-8 and 10-22 ARE ON APPEAL

1. A biochemical analyzing method comprising the steps of

fixing probes selected in advance on a substrate;

binding a target with at least one of the probes using a specific binding reaction to capture the target;

fractionating a combined body of the probe, the captured target and a substance derived from a living organism other than the captured target which is bound with the probe due to a similarity in structure;

detecting only a fractionated target; and

quantitatively analyzing the detected target, wherein the probes are spotted on the substrate and fixed thereon, and the combined body of the probe, the captured target and the substance derived from a living organism other than the target is electrophoresed, thereby being fractionated,

wherein during the fractionating, the combined body of the probe and the captured target and the substance derived from a living organism other than the target is separated into a plurality of fractions based on molecular weight.

2. The biochemical analyzing method in accordance with Claim 1, wherein the target is bound with the at least one probe using hybridization.

4. The biochemical analyzing method in accordance with Claim 1, wherein the combined body of the probe, the captured target and the substance derived from a living organism other

than the target is electrophoresed in a direction at an angle with the surface of the substrate, thereby being fractionated.

5. The biochemical analyzing method in accordance with Claim 4, wherein the combined body of the probe, the captured target and the substance derived from a living organism other than the target is electrophoresed in gel adjacent and in contact with the substrate, thereby being fractionated.

6. The biochemical analyzing method in accordance with Claim 5, wherein the combined body of the probe, the captured target and the substance derived from a living organism other than the target is electrophoresed in a block of gel adjacent to the substrate, thereby being fractionated.

7. The biochemical analyzing method in accordance with Claim 4, wherein the combined body of the probe, the captured target and the substance derived from a living organism other than the target is electrophoresed in a plurality of capillaries adjacent to and in contact with the substrate, thereby being fractionated.

8. The biochemical analyzing method in accordance with Claim 7, wherein the plurality of capillaries are filled with a material capable of forming a membrane filter or a gel.

10. The biochemical analyzing method in accordance with Claim 1, wherein the probes are one-dimensionally spotted on the substrate to form a plurality of spots and are fixed thereon.

11. The biochemical analyzing method in accordance with Claim 1, wherein the probes are two-dimensionally spotted on the substrate to form a plurality of spots and are fixed thereon.

12. The biochemical analyzing method in accordance with Claim 1, wherein the target consists of a gene.

13. The biochemical analyzing method in accordance with Claim 1 which further comprises a step of labeling the target with a fluorescent substance.

14. The biochemical analyzing method in accordance with Claim 13, wherein the target is labeled with the fluorescent substance prior to binding the target with the probes.

15. The biochemical analyzing method in accordance with Claim 13, wherein the combined body of the captured target, the probe and the substance derived from a living organism other than the target is labeled with the fluorescent substance after the combined body of the probe, the captured target and the substance derived from a living organism other than the target is fractionated.

16. The biochemical analyzing method in accordance with Claim 1 which further comprises a step of labeling the target with a labeling substance which generates chemiluminescent emission when it contacts a chemiluminescent substrate.

17. The biochemical analyzing method in accordance with Claim 16, wherein the step of labeling occurs prior to said binding step.

18. The biochemical analyzing method in accordance with Claim 16, wherein the step of labeling occurs after the fractionating step.

19. The biochemical analyzing method in accordance with Claim 10, wherein the fractionated targets are two-dimensionally scanned and light released from the targets is detected, thereby performing quantitative analysis.

20. The biochemical analyzing method in accordance with Claim 10, wherein light released from the fractionated targets is detected using an area sensor and quantitative analysis is performed.

21. The biochemical analyzing method in accordance with Claim 11, wherein the fractionated targets are three-dimensionally scanned and light released from the targets is detected, thereby performing quantitative analysis.

22. The biochemical analyzing method in accordance with Claim 1, wherein targets electrophoresed to positions in accordance with the kinds of the targets are quantified and analyzed.

EVIDENCE APPENDIX:

None.

RELATED PROCEEDINGS APPENDIX

None.

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of

Nobuhiko OGURA

Appln. No.: 09/944,175

Confirmation No.: 9850

Filed: September 4, 2001

Docket No: Q65952

Group Art Unit: 1639

Examiner: Christopher M. GROSS

For: BIOCHEMICAL ANALYZING METHOD, BIOCHEMICAL ANALYSIS APPARATUS, BIOCHEMICAL ANALYSIS UNIT USED THEREFOR AND TARGET DETECTING APPARATUS FOR DETECTING TARGET FROM BIOCHEMICAL ANALYSIS UNIT

SUBMISSION OF APPEAL BRIEF

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith please find an Appeal Brief. The statutory fee of $510.00 is being charged to Deposit Account No. 19-4880 via EFS Payment Screen. The USPTO is also directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

Chid S. Iyer / Bruce S. Kramer Reg. No. 33,725

Chid S. Iyer
Registration No. 43,355

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Date: November 12, 2007